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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,187	02/06/2001	Peter Robert Baum	2873-US-CIP	9057
22932 7590 06/18/2007 IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 06/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/778,187	Applicant(s) BAUM ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-35 and 55-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-35 and 55-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to ILIA OUSPENSKI, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 05/18/2005 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/18/2005 has been entered.

3. Applicant's amendment/remarks, filed on 05/18/2005, are acknowledged.

Claims 1 – 19, 36, and 55 – 63 have been cancelled.

Claims 20 – 35 and 37 – 54 are pending.

4. This Office Action will be in response to Applicant's amendment and arguments, filed on 05/18/2005.

The rejections of record can be found in the previous Office Action, mailed on 06/11/2004.

The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

5. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20 – 35 and 46 – 54 stand rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for an isolated polypeptide comprising the recited amino acids of SEQ ID NO:2 or SEQ ID NO:4, or encoded by a nucleic acid of SEQ ID NO:1 or SEQ ID NO:3, does not reasonably provide enablement for the following:

A. an isolated polypeptide comprising an amino acid sequence that is at least 90% identical to SEQ ID NO:2 or SEQ ID NO:4;

B. an isolated polypeptide comprising a fragment of the recited amino acid sequences of SEQ ID NO:2 or SEQ ID NO:4; or

C. an isolated polypeptide encoded by a nucleic acid which is capable of hybridizing, under the recited conditions, to the complement of SEQ ID NO:1 or SEQ ID NO:3.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is maintained essentially for the reasons of record.

Applicant's arguments have been fully considered but have not been found sufficiently convincing.

Applicant argues that the specification provides working examples of two sequences of LDCAM and distinguishes them from related proteins; identifies major structural elements of these proteins, and provides guidance to making conservative substitutions and testing the resulting variants for binding to LDCAM. Applicant further argues that since such experimentation is routine in the art, the quantity of experimentation required to obtain the claimed variants is not undue.

This is not found sufficiently persuasive, essentially for the reasons of record set forth in the previous office actions. Although there is some guidance as to the structural features of the proteins and general methods of creating variants and testing them for binding, the experimentation required is still deemed to be undue, given the vast number of possible variants and the unpredictability of the art.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

7. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 20 – 35 and 37 – 54 are rejected under **35 U.S.C. 102(e)** as being anticipated by Filvaroff et al. (US Patent No. 6,642,360; see entire document).

Filvaroff et al. teach an isolated polypeptide PRO355 (SEQ ID NO:61) (see entire document, in particular, e.g. the Sequence Listing, Figure 24, and column 13), and variants of this polypeptide (e.g. columns 17 – 18). The PRO355 polypeptide is 100% identical to the instant polypeptide of SEQ ID NO:2 from position 39 to position 442. PRO355 differs from the instant polypeptide of SEQ ID NO:2 only by an internal deletion of two amino acid residues in the signal sequence corresponding to positions 24 and 25 of instant SEQ ID NO:2. PRO355 therefore also is a polypeptide 100% identical to the instant polypeptide of SEQ ID NO:4 from position 8 to position 423. PRO355 differs from the instant polypeptide of SEQ ID NO:4 by an internal deletion of two amino acids in the signal sequence corresponding to positions 6 and 7 of instant SEQ ID NO:2 and by an additional amino acid at the C terminus.

Applicant's Declaration under 37 CFR 1.131 by Drs. Baum and Fanslow, filed on 05/18/2005, is acknowledged, but is ineffective to overcome the present rejection, for the following reasons.

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Applicant's Declaration is not sufficient in scope of disclosure, relative to the scope of the instant claims and the scope of teachings in the prior art.

The instant claims encompass in their breadth variants and fragments of the polypeptide of SEQ ID NO:2. Likewise the prior art reference teaches variants and fragments of the PRO355 polypeptide. However, the Declaration is limited in scope to the sequence of human LDCAM of SEQ ID NO:2. As such, the Declaration is insufficient in scope to overcome the teachings of the prior art reference of Filvaroff et al. See MPEP §§715.02 and 715.03.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

9. Conclusion: no claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

Art Unit 1644

June 10, 2007


PHILLIP GAMBEL, PH.D. JD
PRIMARY EXAMINER
1644
6/10/07